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Consultations Being Sought on Revised LLP Draft Policy

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Report Highlights:
Based on the feedback received by industry stakeholders during its 2012 public consultation on Canada's "Proposed Domestic Policy on the Management of Low-Level Presence of Genetically-Modified Crops and Imports and its Associated Implementation Framework", Canada has published revisions to the original draft and is seeking comment on these changes. A number of aspects requiring further analysis have been identified, including setting a general threshold level. This report contains the full explanatory background and revised draft policy published on the Agriculture and Agri-Food Canada website.

April 2015

Preamble

The Government of Canada held a public consultation on Canada's 2012 "Proposed Domestic Policy on the Management of Low-Level Presence of Genetically-Modified Crops and Imports and its Associated Implementation Framework" from November 6, 2012 to January 19, 2013.

Feedback received through this consultation has led to a number of proposed changes to the 2012 draft policy and implementation framework. At the same time, a number of aspects requiring further analysis have been identified. The policy and implementation framework will not be finalized until these outstanding issues are addressed.

Changes in the draft include:

- When the policy eligibility criteria are met, the **level for low-level presence (LLP) in imports below which a risk assessment will not normally be required has been set at 0.2%.** In the previous draft of this policy, this level was described as the Action level and it had not been set. This level will help to proactively mitigate potential risks posed by trace levels of LLP resulting from dust or other sources such as discontinued genetically-modified (GM) crops. Above this level, LLP risk assessments must be proactively completed to be eligible for the higher threshold level to apply.
- **One Threshold Level** will be set for all crops, rather than crop-specific threshold levels. Expert advice will be taken into account in setting this threshold level. This approach will significantly reduce potential for confusion with respect to application of the threshold level and will simplify implementation of the policy.
- To facilitate oversight activities to verify LLP levels in imports, **a requirement for detection methods and reference material** is now included as a condition for the policy to apply.
- A **questionnaire will be used to** assess if foreign regulatory authorities' food safety assessment procedures are consistent with the *Codex Guideline for the Conduct of a Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*. This approach will be both proactive and transparent.
- The policy and implementation framework have been clarified to indicate that **measurement uncertainty** unavoidably introduced through laboratory testing activities **will be taken into account** when determining the level of LLP in imported grain.
- To be consistent with Canada's legislative framework, revisions were made to clarify that **risk-commensurate enforcement actions** would be taken when LLP is detected below 0.2% or, when applicable, the Threshold Level.
- Other minor changes were made to improve clarity and reduce repetition.

Outstanding policy and implementation issues to be resolved include, but are not limited to:

- Setting the threshold level
- Determining an efficient, effective, and proactive LLP risk assessment process based on Codex

LLP Food Safety Assessment guidance
- Determining an approach to improve predictability for processed products, including single ingredient processed products
- Determining how to apply LLP levels to stacked events (defined as crops in which two or more GM events have been combined in one plant)

Resolving these outstanding complex issues will require further analysis and work with stakeholders and international partners. A decision regarding when to implement the policy will take place once the policy is finalized, and will take into account potential risks and benefits.

Comments on this revised draft policy and implementation framework may be sent to LLP-PFC@agr.gc.ca

The revised draft policy in full on the following page as well as at the following URL address:

http://www.agr.gc.ca/eng/about-us/public-opinion-and-consultations/update-on-domestic-low-level-presence-policy-development/revised-draft-policy-on-the-management-of-low-level-presence-of-genetically-modified-crops-in-imported-grain-food-and-feed-and-its-associated-implementation-framework-for-grain/?id=1425927067839

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Background

1. Governments as well as public and private institutions around the world are actively seeking ways to increase agricultural productivity and make other useful improvements to crops. In support of these efforts, it is expected that the number and variety of genetically modified (GM) products commercialized will continue to increase.
2. Once a GM crop is authorized for commercial use in a foreign jurisdiction, trace amounts of that crop may become mixed with other varieties of the same crop or other crops in that jurisdiction. This can happen during the cultivation, harvest, transportation, and storage of the GM crop. Even when best management practices are strictly followed, it is often difficult to prevent this from occurring. In addition, approved GM crops that have been discontinued or are not currently in commercial production, may persist at low levels in commodity and seed supplies for many years, despite stringent measures to eliminate them. As a result, a GM crop that is not approved in the importing jurisdiction may unintentionally be present at low levels in the grain, food or feed products exported to that jurisdiction. This is what is called low-level presence (LLP).
3. As a result of the lack of synchronization in the approvals of new GM crops by countries and the expected increase in the commercialization of GM crops around the world, the likelihood of LLP is expected to increase. Canada will continue to actively work with other countries on addressing the issue of asynchronous approvals with a view of minimizing unnecessary trade disruptions.
4. Under the Canadian regulatory framework, the presence of an unauthorized GM crop in Canada constitutes non-compliance. When an unauthorized GM crop is detected, the Canadian Food Inspection Agency (CFIA) and Health Canada (HC) evaluate the risk posed by the presence of the unauthorized GM crop and then determine the most appropriate risk-based response. The goal is to maintain food, feed and environmental safety, while using the most appropriate level of intervention to return the situation to compliance. A return to compliance can include:
    - the authorization of the non-compliant product for food, feed and environmental release in Canada; or,
    - the removal of the non-compliant product from Canada.
5. The regulatory response may include: control actions such as product recall and enforcement actions such as detaining or seizing products. Currently in LLP situations, even if a risk assessment shows that the product is unlikely to pose a risk to the health and safety, there is an obligation to return the situation to compliance.
6. Enforcement actions taken when an unauthorized GM crop is detected may disrupt trade and increase costs to Canadian industry and to governments. Under Canada's current approach, such disruptions and costs could occur even in situations where the unauthorized GM crop, present at low levels, is unlikely to pose a risk to human or animal health or to the environment.
7. While the Government of Canada continues to encourage developers of new GM crops to seek full authorization in Canada, the Government recognizes that internationally synchronized approvals of GM crops may not always be feasible. Therefore, the Government of Canada is developing a policy and implementation framework that provides a more predictable, pragmatic approach to managing LLP in imported grain, food and feed.

8. The revised policy and framework set out the Government of Canada's proposed direction for managing occurrences of LLP. They include the specific conditions by which potential risks posed by LLP in imports can be proactively assessed and mitigated for GM crops and the resulting low risk enforcement response actions.

Revised draft policy for the Management of Low-Level Presence of Genetically Modified Crops in Imported Grain, Food and Feed

Note: This document includes revisions to the September 2012 document "Proposed Domestic Policy on the Management of Low-Level Presence of Genetically-Modified Crops in Imports and its Associated Implementation Framework"

1. Policy statement

- 1.1 Upon detection of unauthorized GM crops in grain, food or feed products imported into Canada, it is the policy of the Government of Canada to take action commensurate with the potential risk posed by the LLP, without unduly disrupting trade.

2. Definitions

- 2.1 For the purpose of this policy:
  - **Genetically modified (GM)** refers to plants that have been modified using recombinant DNA technology.
  - **GM crop** refers to a plant with one or more specific or novel traits that have been introduced via recombinant DNA technology.
  - **Low-level presence (LLP)** is the unintended presence, at low levels, of unauthorized GM crops in imported grain, food or feed; where the GM crop is authorized for food use in one or more foreign jurisdictions but is not authorized in Canada.
  - Additional definitions pursuant to this Policy are found in the glossary in Appendix 1.

3. Objective(s)

- 3.1 The objectives of the policy are to:
  - minimize disruptions to trade while protecting the health and safety of humans, animals and the environment;
  - facilitate an effective and efficient risk-based approach to managing LLP; and,
  - provide transparency and predictability for importers and exporters.

4. Guiding principles

- 4.1 In managing situations of LLP, the Government of Canada will follow these principles:
  1. The safety of human food, animal feed and the environment in Canada is paramount.
  2. Risk management decisions and enforcement actions to address LLP occurrences are science-based and risk-based.
  3. Risk management approaches for LLP are designed to proactively mitigate potential risks and be resource efficient for both government and industry.

4. Encourage compliance with Canada's domestic regulatory system (for example, full authorization of GM products).
5. Risk management decisions and enforcement actions minimize unnecessary trade disruptions to the extent possible.
6. Risk assessments for LLP are conducted in a manner that is consistent with international guidance on managing LLP.

5. Scope

- 5.1 The LLP policy applies to all imported grain, and imported food and feed products derived from grain, which contain LLP where:
  - the GM crop has been approved for use as food in at least one foreign jurisdiction;
  - Canada has recognized that safety assessments conducted by the regulatory authority in that foreign jurisdiction are consistent with *Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*; and
  - a detection method is publically available or has been submitted to the CFIA and reference material is made available to the CFIA upon request for the GM crop.
- 5.2 Recognizing that most components of a food safety assessment also apply to feed, a foreign feed assessment is not required for an unauthorized GM crop to be considered LLP.
- 5.3 The Policy does **not** apply to:
  1. seed intended for propagation in the environment;
  2. GM fruits and vegetables;
  3. adventitious presence which is defined, for the purpose of this Policy, as the unintended release of GM crops that have not been authorized for use in **any** foreign jurisdiction;
  4. GM animals and micro-organisms;
  5. other GM crops modified to produce plant-made pharmaceutical or industrial products unless approved for food and feed use;
  6. GM crops for which there is reason to believe that LLP may pose a risk to the safety of human food, animal feed or the environment; and,
- 5.4 The Policy does not supersede any varietal purity, organic or other such agricultural standards.

6. Risk management for grain

- 6.1 A stepwise risk-based approach is taken to manage LLP in grain which consists of two levels:
  1. When LLP in grain of all crop types is detected at concentrations below 0.2%, the enforcement response would reflect the negligible risk posed by the non-compliance, including actions such as issuing a letter to the regulated party to inform them of the detection results and to provide information about the LLP Policy and Framework, the

applicable regulatory requirements, as well as information about the approval process for GM products in Canada. This is intended to address potential trace amounts of LLP resulting from dust or other sources. Since the food safety assessment that the GM crop has passed is consistent with the *Codex Guideline for the Conduct of a Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*, the potential risks posed by trace levels of LLP (up to 0.2%) are mitigated.

2. A **Threshold Level** of X%[Footnote 1] will apply to LLP in grain of all crop types. The Threshold Level is the maximum considered to be low, unintentional presence of GM crops in imported grain, food and feed. The Threshold Level applies only when a risk assessment carried out by Canadian authorities has proactively determined that the presence of the GM crop at the proposed level is unlikely to pose risk to food, feed or environmental safety. The enforcement response would reflect the negligible risk posed by the non-compliance, including actions such as issuing a letter of non-compliance.

- 6.2 When levels exceed the Threshold Level, given that the risk posed by the imported product is unknown, control actions on the product may be taken (for example, product recall). A reactive assessment for the specific situation will be conducted to determine the appropriate control and/or enforcement response.

7. Risk management for processed products

- 7.1 For processed grain and other further refined processed food or processed feed products derived from grain, the 0.2% and Threshold Levels set for grain will apply indirectly. This is because the concentration of LLP in imported processed grain products will change from the level in the original grain, depending of the processing procedures used to transform the grain. In this context, if an unauthorized GM crop is detected in a processed grain product intended for food or feed use, an assessment will be conducted for the specific incident to determine the most appropriate response. The 0.2% and Threshold Levels for LLP in grain will be taken into consideration, as will any applicable risk assessments conducted for LLP of that GM crop in grain, prior to taking enforcement action on the imported processed grain product.

8. Authorities

- 8.1 All foods sold in Canada are subject to the *Food and Drugs Act* and its associated Regulations. Novel foods, including those derived from GM crops, are specifically subject to Division 28 of part B of the *Food and Drug Regulations*.
- 8.2 Livestock feeds manufactured in, sold in or imported into Canada are regulated under the *Feeds Act* and its associated Regulations. Novel feeds or feed ingredients, including those derived from GM crops must undergo a pre-market safety assessment and be approved before they can be manufactured in, sold in or imported into Canada as a feed ingredient.
- 8.3 Under the *Canada Grain Act*, the Canadian Grain Commission has authority over 21 grains designated as grain in the*Canada Grain Regulations* and imported into Canada.

9. Roles and responsibilities

- 9.1 Regulated parties are responsible for:
  1. ensuring that products imported into Canada comply with relevant requirements;
  2. informing the Government of Canada of GM crops that have been approved by at least one foreign jurisdiction and that could possibly be imported at low levels into Canada;
  3. providing the required information to the CFIA and HC for the completion of the proactive LLP risk assessments; and
  4. providing detection methods and reference materials to the CFIA.
- 9.2 Agriculture and Agri-Food Canada (AAFC) is responsible for reviewing and maintaining this policy.
- 9.3 The Canadian Food Inspection Agency (CFIA) and Health Canada are responsible for administering their mandated legislation and for implementing this policy.

10. Review

- 10.1 AAFC will review this policy, including an evaluation of its success in achieving its objectives. The first review will take place two (2) years after the policy is implemented. Subsequent reviews will take place every five (5) years, or earlier as appropriate.

11. References

- 11.1 Current Canadian approach to managing cases of unauthorized presence of plants (and their products) derived through biotechnology in food, livestock feed, and the environment
- 11.2 Codex Alimentarius Commission CAC/GL 45-2003 Guideline For The Conduct Of Food Safety Assessment Of Foods Produced Using Recombinant-DNA Plants (external PDF) (including Annex 3: Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food)

12. Implementation framework

- 12.1 The policy is supported by an implementation framework (Section 14 onward) that outlines the approach to implementation and may be amended from time to time.

13. Inquiries

- 13.1 AAFC is the contact point for this policy. Any inquiry should be directed to: LLP-PFC@agr.gc.ca.

Revised Draft Implementation Framework to Manage Low-Level Presence in Grain

14. Introduction

- 14.1 To support implementation of the Revised Draft Policy for the Management of Low-Level Presence of Genetically Modified Crops in Imported Grain, Food and Feed, this revised draft LLP Implementation Framework sets out how Health Canada and the Canadian Food Inspection Agency (CFIA) will implement the LLP Policy for grain. The LLP Implementation Framework sets out how Canada proposes to manage LLP in grain in specific situations where risk to human or animal health or the environment is proactively mitigated. This framework also sets out monitoring activities and clarifies the risk-based enforcement response when LLP is detected in imported grain.
- 14.2 This framework describes how the LLP policy objectives of transparency, predictability, and efficient and effective risk management are achieved for imported grain. It is consistent with the CFIA's *Compliance and Enforcement Operational Policy*[Footnote 2] which requires compliance management to be guided by the principles of risk management, fairness, impartiality, and transparency, and the powers and authorities set out in the relevant legislation.
- 14.3 The CFIA uses a continuum of control and enforcement actions to respond to non-compliances with responses able to be directed at the product and/or the regulated party. Where an enforcement response is required, the CFIA has the flexibility to determine the most appropriate actions depending on the potential harm, intent, past compliance history, and risk considerations of the specific non-compliance.
- 14.4 Control actions are directed at the product (for example, recall) and are taken to mitigate risk when imported grain poses, or may pose a risk. Enforcement actions are taken when non-compliance is determined and can range from actions directed at the regulated party (for example, letter of non-compliance) or actions directed at the product (for example, seizure/detention, product recall).
- 14.5 Under the Canadian legislative framework, the presence of an unauthorized GM crop constitutes non-compliance. Recognizing that in many situations LLP in grain imports is unlikely to pose a risk to human or animal health or the environment, a commensurate enforcement response would be appropriate. To improve predictability and transparency with respect to actions taken when LLP is detected in imports, **this framework elaborates on the specific criteria by which risks posed by LLP can be proactively assessed and mitigated for GM crops.** When these specific criteria are met, consistent and risk-commensurate enforcement actions in turn help to minimize trade disruptions while protecting the health and safety of humans, animals and the environment.
- 14.6 The LLP Implementation Framework includes a risk management approach to proactively assess and mitigate risks posed by LLP in grain imported into Canada for food or feed. Further, the framework outlines a risk-based monitoring approach to verify that imported grain meets Canadian legislative requirements. The framework also identifies the risk-commensurate enforcement actions that could be expected in various situations when LLP is detected.

15. Application

- 15.1 This framework applies to imported whole grain (for example, cereals, oilseeds, pulses, buckwheat, corn, and rice) containing primarily a single species of grain, intended to be used in or as food or feed.
- 15.2 For the presence of an unauthorized GM crop to be considered eligible for the LLP policy to apply, the following three overarching criteria must be met:
    1. the GM crop must be approved in at least one foreign jurisdiction in accordance with the *Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003), hereafter referred to as the **Codex Guideline**;
    2. Canada must have determined that the food safety assessment process in the foreign jurisdiction that approved the GM crop is consistent with the Codex Guideline (refer to Section 17); and
    3. Appropriate test methodologies must be publicly available or provided directly to the CFIA, and reference materials for the detection and identification of the specific GM crop must be made available to CFIA upon request (refer to Section 18).
- 15.3 When it is determined that the unauthorized GM crop **does not meet all of the above assessment criteria or** when there are reasonable grounds to believe that a GM crop may pose a risk to the safety of food, feed or the environment, the LLP Policy and its implementation framework do **not** apply.

16. Risk management approach

- 16.1 The risk management approach:
    1. Sets out the specific proactive risk mitigation criteria that must be adhered to in order for the policy to apply when LLP is detected (refer to Section 15).
    2. Considers minimal risks posed by trace amounts (for example, dust) of LLP are mitigated when:
        1. the GM crop has been verified by Health Canada and the CFIA to meet **all** of the criteria set out in Section 15.2 thus providing confidence that the LLP is unlikely to pose a risk to food, feed, or the environment; and
        2. the total concentration of LLP in imported grain is less than or equal to 0.2%[Footnote 3] thereby minimizing the potential exposure to humans, animals and the environment.

    In these situations, the enforcement response to non-compliance would reflect the negligible risk posed by the shipment. Risk-commensurate enforcement action would be taken such as issuing a letter to the regulated party to inform them of the detection results and to provide information about the LLP Policy and Framework, the applicable regulatory requirements, as well as information about the approval process for GM products in Canada.

3. Sets a maximum **Threshold Level** of LLP of X%[Footnote 4] which is considered to be low unintentional presence of GM crops. Potential risks posed by LLP up to the Threshold Level are proactively mitigated when:
    1. GM crop has been verified by Health Canada and the CFIA to meet **all** of the criteria set out in Section 15.2;
    2. a LLP risk assessment of the GM crop has been completed by the Government of Canada prior to detection of the GM crop (refer to Section 19 for additional details); and
    3. the total concentration of LLP in imported grain is less than or equal to X%[Footnote 3], [Footnote4].

    In these situations, the risk is considered negligible and as such, commensurate enforcement actions would be taken such as issuing a letter to the regulated party to inform them of the detection results and to provide information about the LLP Policy and Framework, the applicable regulatory requirements, as well as information about the approval process for GM products in Canada.

4. Specifies that the potential risk of an imported product is unknown or may pose a risk when:
    1. the unauthorized GM crop does **not** meet **all** of the criteria set out in Section 15.2; **or**
    2. when there are reasonable grounds to believe that a GM crop may pose a risk to the safety of food, feed or the environment.

    In such situations, control actions on the product may be taken (for example, product recall). A reactive assessment of the specific situation will be conducted to determine the most appropriate control and/or enforcement response (for example, seizure/detention).

- 16.2 Appendix 2 illustrates the LLP risk management approach for grain described in this framework.

17. Codex consistency assessments

- 17.1 A Codex Consistency Assessment completed in advance of an LLP incident verifies that the GM food safety assessment process that was completed to authorize food or feed use in the foreign jurisdiction was completed in a manner consistent with the Codex Guideline. This proactive verification provides confidence that if trace levels of LLP of GM crops approved by that jurisdiction are detected in Canadian imports of grain they are unlikely to pose a risk to food or feed safety in Canada.
- 17.2 To assess the consistency of a foreign jurisdiction's GM food safety assessment process with the Codex Guideline, a questionnaire must be completed by the appropriate competent authority of that jurisdiction and submitted to Health Canada. Countries with GM crops approved

for feed or food use that have not been authorized in Canada will be encouraged to complete a Codex Consistency Questionnaire.

- 17.3 The Codex Consistency Questionnaire will ask foreign jurisdictions to provide a detailed description of their GM food safety assessment process and regulatory framework, and to clearly demonstrate how their process is consistent with the Codex Guideline.
- 17.4 Health Canada will review completed questionnaires and inform the relevant competent authorities of the outcome of the Codex Consistency Assessments, including if clarifications are required. A list of foreign jurisdictions verified as having regulatory frameworks that are consistent with the Codex Guideline will be published online. Foreign jurisdictions will be reassessed, as required, to verify continued consistency with the Codex Guideline.
- 17.5 When LLP is detected in imported grain, the CFIA will refer to publicly available information about GM crop approvals (for example, Food and Agriculture Organization (FAO) GM Food Platform, the Organisation for Economic Co-operation and Development(OECD) database and the Biosafety Clearing House) and cross-reference this information with Canada's list of foreign jurisdictions with positive Codex Consistency Assessments to determine whether the LLP policy will apply to a given GM crop.

18. Test methods and reference material

- 18.1 To support monitoring of LLP in imported grain and the application of the LLP policy, detection methods and reference material of GM crops that may be present in imported grain must be provided to the CFIA or readily available.
- 18.2 Detection Methods must be directly provided to the CFIA or publicly available and must be:
    1. validated;
    2. specific to the GM crop event;
    3. capable of accurate detection, identification and quantification of the specific GM crop event across a dynamic range that includes 0.2% and the threshold level, with no cross reactivity to other GM crop events or products; and
    4. capable of implementation as part of routine testing with no proprietary equipment, reagents or software.
- 18.3 Appropriate reference material must be made available to the CFIA upon request. Ideally, Certified Reference Material[Footnote 5] should be available. If Certified Reference Material is unavailable, suitable reference material must be available. This is any material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

19. Threshold level

- 19.1 The Threshold Level sets the maximum concentration of LLP that is considered to be low, unintentional presence of GM crops.

- 19.2 The Threshold Level applies to grain of all crops and takes into account the realities of modern agricultural production and commodity trade, recognizing that small amounts of unintentional commingling can occur during crop production, transportation, bulk handling, conditioning, and storage.
- 19.3 The Threshold Level will be set at X%[Footnote 6] total concentration of LLP in imported grain for use in or as food or feed. The concentration of LLP is determined as the percentage by weight of the sample tested.[Footnote 7]
- 19.4 Potential risks posed by LLP are proactively mitigated when:
  1. The total concentration of LLP is **less than or equal to** the Threshold Level (X%[Footnote 6]);
  2. The GM crop(s) has been verified by Health Canada and the CFIA to meet all of the criteria set in Section 15.2; and
  3. A food and feed LLP risk assessment of the GM crop(s) has been completed by Health Canada and the CFIA **prior** to detection in an imported grain shipment and has shown that LLP of this GM crop is unlikely to pose a risk to the safety of humans, animals or the environment at the Threshold Level.

  In these situations, the enforcement response to the non-compliance would reflect the negligible risk posed by the shipment. Risk-commensurate enforcement action would be taken such as issuing a letter to the regulated party to inform them of the detection results and to provide information about the LLP Policy and Framework, the applicable regulatory requirements, as well as information about the approval process for GM products in Canada.

- 19.5 When the total concentration of LLP is **greater** than the Threshold Level, the potential risk posed by the imported product is unknown and as such control actions on the product may be taken (for example, product recall). Health Canada and the CFIA would assess the situation and determine the appropriate control and enforcement response to mitigate potential risks and address the non-compliance.
- 19.6 Importers, developers, or other interested parties should proactively submit data for risk assessments for GM crop(s) that are not approved in Canada so that the Threshold Level will apply when LLP is detected in imported grain.

Threshold risk assessments

- 19.7 In order for the Threshold Level to apply, Health Canada and the CFIA must have completed a risk assessment of the GM crop and determined that the GM crop is unlikely to pose a safety risk when present at concentrations up to the Threshold Level.
- 19.8 For a risk assessment to be completed, the following must be submitted to the CFIA: a complete data package in English or French as per the data requirements outlined in Annex 3 of the Codex Guideline: *Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food*[Footnote 8], and the fee, if a fee has been set[Footnote 9]. The CFIA will forward the complete data package to Health Canada; Health Canada will conduct a food risk assessment.

- 19.9 Health Canada will conduct a risk assessment of the GM crop, in accordance with Annex 3 of the Codex Guideline: *Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food*, to determine if LLP of the GM crop in food at concentrations up to the Threshold Level is likely to pose a risk when it is used in or as **food**.
- 19.10 The CFIA will conduct a risk assessment of the GM crop to determine if LLP of the GM crop at concentrations up to the Threshold Level is likely to pose a risk when it is used in or as **feed**.
- 19.11 In cases where the submitted data package is not sufficient to assess the risks posed by LLP of the GM crop in food products, as per Annex 3 of the Codex Guideline, or in feed products (for example, when the components of the plant used in feed are different from those used in food), additional information may be requested.

20. Monitoring activities

- 20.1 The CFIA will monitor to verify compliance with Canadian regulatory requirements in accordance with appropriate legislation. As per its *Compliance and Enforcement Operational Policy*, the CFIA takes a risk-based approach to compliance oversight and enforcement.
- 20.2 Frequency of monitoring of imported grain will be consistent with the potential risk posed. When the conditions set in sections 15 and 16 are met, the potential risk posed by the LLP would be considered minimal. However, other factors, such as the importer's compliance history, and foresight analysis to identify GM crops that have been approved in other foreign jurisdictions and therefore may be present in imported grain, are also considered when establishing oversight activities.
- 20.3 The CFIA will monitor imported grain to verify compliance with regulatory requirements. Monitoring activities may be carried out at the border when the imported product is entering Canada, or post-border, when the imported product arrives at its destination. In addition, the CFIA will utilize its complaints and investigations processes to respond to complaints regarding compliance.
- 20.4 Monitoring samples of grain shipments will be taken and analyzed for the presence of unapproved GM crops including LLP. The standard principles of measurement uncertainty resulting from laboratory testing variation will be applied to the raw test results when they are interpreted to determine the detected LLP levels.

Appendix 1: Glossary

For the purposes of the proposed Policy and Framework the following terms are defined as follows:

Adventitious presence

Adventitious presence is defined as the unintended presence of research or "pre-commercial" or otherwise unauthorized material which has not been assessed in any foreign jurisdiction.

Codex Alimentarius

The Codex Alimentarius Commission, established by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) in 1963 develops harmonized international

food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair trade practices in the food trade.

Codex Alimentarius Commission

The Commission promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations.

Codex Guidelines

The Codex Guidelines refers to the "Codex Guideline for the Food Safety Assessment of Foods derived from Recombinant-DNA plants". The Guideline describes the recommended approach to making safety assessments of foods derived from recombinant-DNA plants where a conventional counterpart exists, and identifies the data and information that are generally applicable to making such assessments. This guideline does not address animal feed (or animals fed with the feed) and does not address environmental risks.

Codex Guidelines – Annex 3 on LLP

The Annex describes the approach to the food safety assessment in situations of low-level presence of recombinant-DNA plant material or in advance of or preparation for such potential circumstances. This Annex also describes data and information sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply.

Control

Action taken on a regulated commodity or thing in response to risk or potential risk to human, animal or plant health, the economy or the environment. Control activities end once the actions taken to mitigate the risk have been effectively implemented.

Enforcement

Any action taken by the CFIA in response to a non-compliance.

Food

Food includes any article manufactured, sold or represented for use as food or drink for human beings, and any ingredient that may be mixed with food for any purpose whatever.

Feed

Feeds are any substance or mixture of substances manufactured, sold or represented for use for consumption by livestock. Only approved ingredients may be used as livestock feed. The list of approved ingredients can be found in Schedules IV and V of the Feeds Regulations. Included in the definition of feed are "novel feeds".

Grain

Grain is seed of cereal, oilseed, pulse or other field crops that is used in whole or in part for human food or livestock feed, either produced in Canada or imported into Canada.

Novel feed

According to Canada's *Feeds Act* and *Feeds Regulations*, a novel livestock feed is composed of or derived from micro-organisms, plants or animal sources that (a) are not approved as livestock feed in Canada (not listed in Schedule IV or V of the *Feeds Regulations*) and/or (b) contain a novel trait. A novel trait is an intentional genetic change that results in a feed that is not deemed equivalent in terms of use and safety to a similar feed set out in Schedules IV or V of the *Feeds Regulations*.

Novel food

According to Canada's *Food and Drugs Act and Regulations*, novel food means:

1. a substance, including a micro-organism, that does not have a history of safe use as a food;
2. a food that has been manufactured, prepared, preserved or packaged by a process that
    1. has not been previously applied to that food, and
    2. causes the food to undergo a major change; and
3. a food that is derived from a plant, animal or micro-organism that has been genetically modified such that
    1. the plant, animal or micro-organism exhibits characteristics that were not previously observed in that plant, animal or micro-organism,
    2. the plant, animal or micro-organism no longer exhibits characteristics that were previously observed in that plant, animal or micro-organism, or
    3. one or more characteristics of the plant, animal or micro-organism no longer fall within the anticipated range for that plant, animal or micro-organism.

Processed products

In this context, processed products mean products intended for food or feed, which have been physically or chemically transformed from grain. This definition does not include agricultural products which have simply been harvested, cleaned, sorted, graded and/or packaged.

Plant with a novel trait

A plant with a novel trait is a plant that contains a trait which is both new to the Canadian environment and has the potential to affect the specific use and safety of the plant with respect to the environment and human health. These traits can be introduced using biotechnology, mutagenesis or conventional breeding techniques.

Reference material

Any material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process. In this context, reference material refers to a genetically pure, representative sample of grain of the GM product in question, used to verify the accuracy of the detection methods.

Risk assessment

Risk assessment is a process that involves determining the likelihood that a specific adverse effect may cause to the environment, livestock or human health following exposure to a particular agent. Risk assessment includes four tasks: hazard identification, hazard characterization, exposure assessment, and risk characterization (a summary and integration of the previous tasks). A risk assessment for a LLP occurrence aims to identify potential hazards and potential routes of exposure and rely on information available at the time, focusing on data pertaining to allergenicity and toxicity of the product, amongst other factors, with the end goal of providing an opinion regarding the likelihood of an adverse effect on health or the environment.

Risk management

Risk management is a term used to collectively describe the activities and considerations involved in addressing, and communicating information about risks to the environment, livestock and human health. Risk management includes a number of inter-related activities: identifying and analyzing options for addressing the risk, developing and implementing a

strategy for managing the risk, monitoring and evaluating the effectiveness of the strategy, and communicating information both about the risk and about the decision-making process.

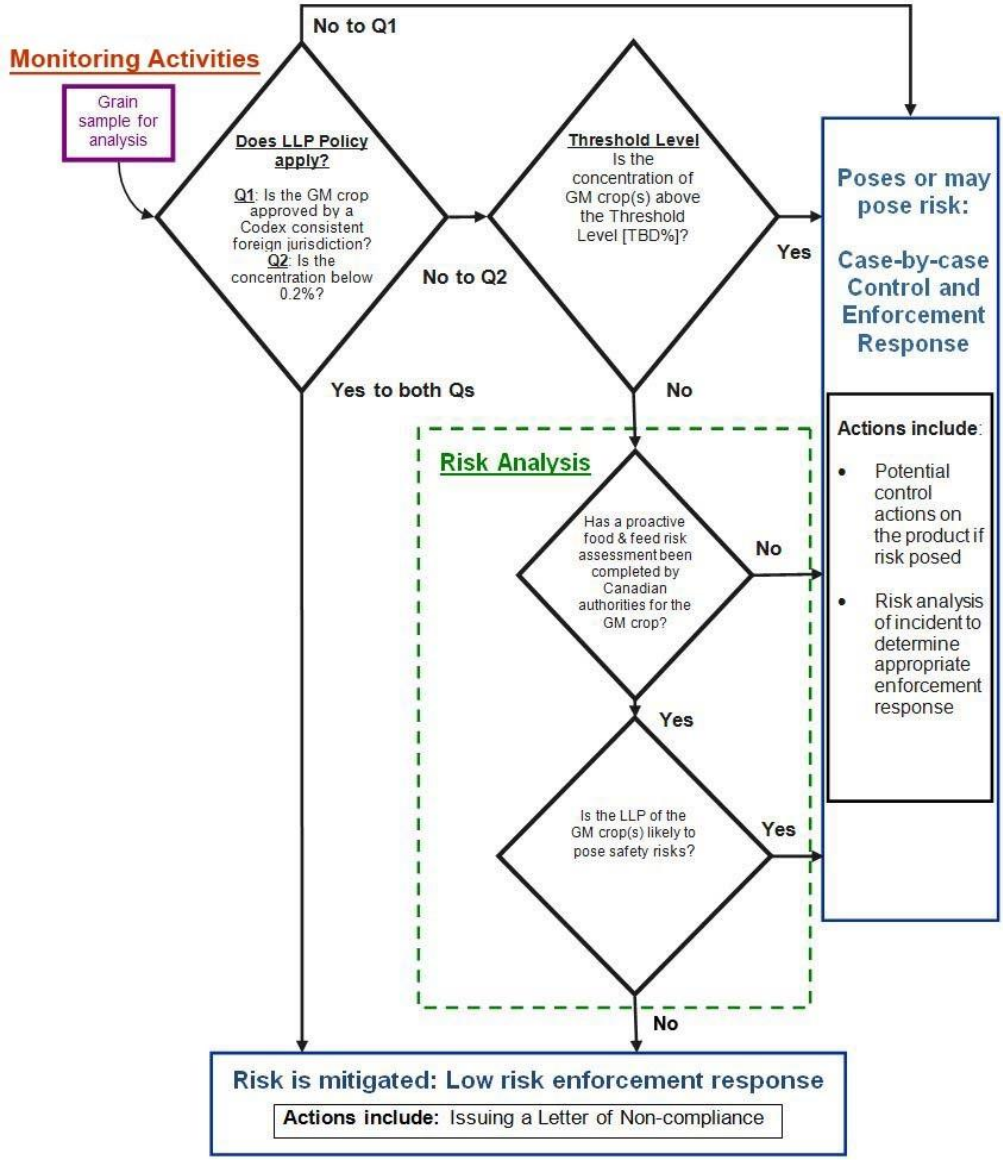
Safety assessment

In contrast to a risk assessment, a safety assessment is meant to establish the safety of a product, or the relative safety of a product in comparison to another similar product which is deemed "safe", with the end goal of determining if a product should be allowed or not for commercial release. In the food and feed context, it is often performed using a comparative approach. In a safety assessment, specific "points to consider" are taken into account in the assessment of hazard and exposure depending on the type of commodity being assessed. The outcome of a safety assessment influences the decision to authorize the product. An authorization indicates that the novel product, including one derived through biotechnology, is as safe and nutritious as its conventional counterpart and therefore can be similarly released and handled.

Stakeholder

A stakeholder is an individual, group, or organization who may be affected by or otherwise interested in a decision or policy.

Appendix 2: Low-level presence risk management approach for grain



Description - Appendix 2

Alternative Format

Help with Alternate Formats

Revised Draft Policy on the Management of Low-Level Presence of Genetically Modified Crops in Imported Grain, Food and Feed and its Associated Implementation Framework for Grain (PDF version, 220KB)

Footnotes

Footnote 1

The Threshold Level has not been set. Health Canada and the CFIA will set the Threshold Level, taking into consideration advice from appropriate experts as well as the overarching objectives and guiding principles stipulated in the LLP policy.

Return to first footnote1referrer

Footnote 2

Compliance and Enforcement Operational Policy

Return to footnote2referrer

Footnote 3

The concentration of LLP is determined as the percentage by weight of the sample tested. The principles of measurement uncertainty will be applied to the raw test result when they are interpreted to determine the level of LLP.

Return to first footnote3referrer
Return to second footnote3referrer

Footnote 4

The Threshold Level has not been set. Health Canada and the CFIA will set the Threshold Level, taking into consideration advice from appropriate experts as well as the overarching objectives and guiding principles stipulated in the LLP policy.

Return to footnote4referrer
Return to second footnote4referrer

Footnote 5

According to ISO, this would be any reference material characterized by a metrologically valid procedure for one or more specified properties, **accompanied by a certificate** that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

Return to footnote5referrer

Footnote 6

The Threshold Level has not been set. Health Canada and the CFIA will set the Threshold Level, taking into consideration advice from appropriate experts as well as the overarching objectives and guiding principles stipulated in the LLP policy

Return to footnote6referrer
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Footnote 7

The principles of measurement uncertainty will be applied to the raw test result when they are interpreted to determine if the result is greater than the Threshold Level.

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Footnote 8

Where a credible international expert body (e.g. a joint WHO and FAO expert committee) has completed a risk characterization of the GM crop, Health Canada and the CFIA will use this risk characterization to inform the risk assessment and management decisions and, therefore, the data package identified in Section 19.8 may not be required

Return to footnote8referrer

Footnote 9

It is expected that a fee to conduct a LLP risk assessment of the GM crop will be set in accordance with and following the process set out in the CFIA's Cost Recovery Policy and Framework.